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Paper for the House Committee Meeting
on 5 November 2010

Legal Service Division Report on
Subsidiary Legislation Gazetted on 29 October 2010

Date of tabling in LegCo : 3 November 2010

Amendment to be made by : 1 December 2010 (or 5 January 2011 if extended by resolution)

Human Organ Transplant Ordinance (Cap. 465)
Human Organ Transplant (Amendment) Regulation 2010 (L.N. 143)
Human Organ Transplant (Appeal Board) Regulation (L.N. 144)

Background

The Human Organ Transplant Ordinance (Cap. 465) (HOTO) was enacted in 1995 to prohibit commercial dealings in human organs intended for transplanting and restrict the transplanting of human organs between living persons and the transplanting of imported human organs. HOTO is amended by the Human Organ Transplant (Amendment) Ordinance 2004 (29 of 2004) (the Amendment Ordinance) which provides, inter alia, that HOTO shall not apply to a regulated product to the extent that it is exempted by the Director of Health (DoH). A "regulated product" means a product containing any structured arrangement of tissues forming part of any human bodily part as specified in the definition of "organ" under HOTO and has been subject to processing.

2. Under the new section 7A(3) of HOTO as added by the Amendment Ordinance, DoH may, on application, exempt a regulated product from the application of HOTO if he is satisfied that -

(a) using the product for transplant purposes is safe and has no adverse impact on public health;

(b) either that the donor of the tissues concerned has given consent to the removal of the tissues for the purpose of producing the product

without coercion or offer of inducement, or that the tissues are removed for the therapy of the donor;

(c) no payment has been made, or is intended to be made to the donor for his supplying the tissues from his body;

(d) all applicable laws of the place where the tissues were obtained or processed have been complied with in obtaining and processing the tissues; and

(e) the circumstances and manner in which the tissues are obtained and processed are not affected by any matter that DoH may consider to be objectionable.

3. A person who is aggrieved by DoH's decision on his application for exemption of regulated products may appeal to the Appeal Board under the new section 7F of HOTO as added by the Amendment Ordinance.

4. The relevant provisions relating to the exemption and appeal (new sections 7A to 7J as added by the Amendment Ordinance) have not yet come into operation pending the establishment of the exemption and appeal mechanism.

Human Organ Transplant (Appeal Board) Regulation (L.N. 144)

5. The Human Organ Transplant (Appeal Board) Regulation (L.N. 144) (Appeal Board Regulation), which is made under section 7J of HOTO, provides for the procedures of lodging, opposing, hearing and determination of an appeal against a decision of DoH on an application for exemption in respect of a regulated product for transplant purpose under the Ordinance. These procedures cover matters including the time limit for lodging appeals, fixing of hearing dates and powers of the Appeal Board in hearing appeals. For the background and a summary of the provisions of the Appeal Board Regulation, Members may refer to paragraph 5 of the LegCo Brief (ref: HWF CR 1/3231/98) issued by the Food and Health Bureau in November 2010.

Human Organ Transplant (Amendment) Regulation 2010 (L.N. 143)

6. Under section 6(1) of HOTO, the Human Organ Transplant Board (the Board) may by regulation require prescribed persons to supply prescribed information to it with respect to transplants that have been or are proposed to be carried out using organs removed from dead or living persons. The relevant prescribed forms are provided in the Schedule to the Human Organ Transplant Regulation (HOTR).

7. The Human Organ Transplant (Amendment) Regulation 2010 (L.N. 143) (Amendment Regulation), which is made under section 6(1) of HOTO, makes amendments to the prescribed forms consequent upon the enactment of the Amendment Ordinance in order to facilitate compliance with the requirements for supplying information to the Board as provided in the Amendment Ordinance. The new Form 1 prescribes the information to be supplied on removal of organ(s) for transplant into another person. The new Form 2 prescribes the information to be supplied on transplant of organ(s). The new Form 3 prescribes the information to be supplied on final disposal of organ(s) removed/imported. Members may refer to para. 6 of the LegCo Brief for a summary of the amendments to the prescribed forms.

Commencement

8. The Amendment Regulation shall come into operation on the day appointed for the commencement of section 21 of the Amendment Ordinance (provisions for amendment of the prescribed forms in the Schedule to HOTR). The Appeal Board Regulation shall come into operation on the day appointed for the commencement of section 11 of the Amendment Ordinance (provisions for exemption of regulated products and appeal board). According to para. 8 of the LegCo Brief, the Administration is planning to commence operation of the remaining provisions of the Amendment Ordinance and the two above items of subsidiary legislation in the fourth quarter of 2011.

Consultation

9. According to paragraph 8 of the Administration's information paper for the Panel on Health Services (LC Paper No. CB(2)1015/09-10(04)) issued in February 2010, the Administration has consulted the Hospital Authority (HA) on the legislative proposals contained in Appeal Board Regulation as it is expected that HA would be the main potential user of organ products and potential applicant for exemption for the regulated products under HOTO. Paragraph 9 of the paper states that the amendments to the prescribed forms are proposed by the Board after consultation with the Department of Health, HA and other private practitioners who are involved in activities relating to organ transplants.

10. The legislative proposals of these two items of subsidiary legislation were referred to the Panel on Health Services for discussion at its meeting on 8 March 2010 (LC Paper No. CB(2)1224/09-10). Whilst members of the Panel did not have any objection to the legislative proposals, questions were raised on the exemption mechanism of organ products from HOTO. Some members also expressed the view that due to the time limit for LegCo members to scrutinise the proposed rules and procedures for appeal under the negative vetting procedure, the Administration should fully consult all stakeholders before tabling the subsidiary legislation .

Recommendation

11. The Legal Service Division is looking at the legal and drafting aspects of the Appeal Board Regulation and the Amendment Regulation and will report further if necessary. Since these two items of subsidiary legislation introduce a mechanism to implement the provisions with respect to the exemption for regulated products under the Amendment Ordinance which was passed in 2004, Members may wish to consider whether to set up a subcommittee to examine them in detail.

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